



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SALZWEDEL *et al.*

Appl. No.: 10/766,528

Filed: January 29, 2004

For: **Inhibition of HIV-1 Replication by  
Disruption of the Processing of the  
Viral Capsid-Spacer Peptide 1  
Protein**

Confirmation No. 2237

Art Unit: 1646

Examiner: *To be assigned*

Atty. Docket: 1900.0430002/LBB/SJE

**Information Disclosure Statement**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents AA1 to AE1 are not provided in accordance with the U.S. Patent and Trademark Office pre-OG notice of July 11, 2003, which states "[t]he Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003." Copies of the remaining documents are provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AL1 and AT8 cited on Form PTO 1449:

Document AL1, Japanese Patent Publication No. JP 1-143832, is in the Japanese language. An unverified English language abstract of document AL1 is attached as document AT13.

Document AT8, Pokrovskii, A.G., *et al.*, is in the Russian language. An unverified English language abstract of document AT8 is attached as document AR12.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter: U.S. Patent Application No. 10/670,797, Allaway *et al.*, filed September 26, 2003, submitted herewith as document AS12; and U.S. Patent Application No. 10/851,637, Salzwedel *et al.*, filed May 24, 2004 as a continuation-in-part of the present application, submitted herewith as AT12.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

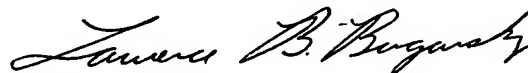
This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

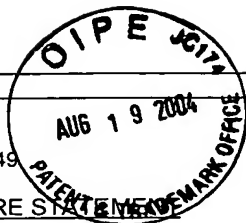
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Attorney for Applicants  
Registration No. 35,086

Date: August 19, 2004

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FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1900.0430002/LBB/SJE

APPLICATION NO.  
10/766,528

FIRST NAMED INVENTOR  
SALZWEDEL *et al.*

FILING DATE  
January 29, 2004

ART UNIT  
1646

### U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,683,195	07/28/1987	Mullis <i>et al.</i>			02/07/1986
	AB1	4,683,202	07/28/1987	Mullis, K.B.			10/25/1985
	AC1	5,468,888	11/21/1995	Bouboutou <i>et al.</i>			05/12/1994
	AD1	5,679,828	10/21/1997	Lee <i>et al.</i>			06/05/1995
	AE1	6,172,110 B1	01/09/2001	Lee <i>et al.</i>			03/02/1999
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### FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	JP 1-143832	06/06/1989	Japan			Yes x No
	AM1	WO 02/26761 A1	04/04/2002	WIPO			Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

### OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Altschul, S.F., <i>et al.</i> , "Basic Local Alignment Search Tool," <i>J. Mol. Biol.</i> 215:403-410, Academic Press Limited (1990).
	AS	1	Brutlag, D.L., <i>et al.</i> , "Improved sensitivity of biological sequence database searches," <i>Comput. Appl. Biosci.</i> 6:237-245, Oxford University Press (1990).
	AT	1	Cleland, J.L., <i>et al.</i> , "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> 10:307-377, CRC Press, Inc. (1993).

EXAMINER

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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449 <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 1900.0430002/LBB/SJE	APPLICATION NO. 10/766,528
	FIRST NAMED INVENTOR SALZWEDEL <i>et al.</i>	
	FILING DATE January 29, 2004	ART UNIT 1646

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>2</u>	Dalgeish, A.G., <i>et al.</i> , "The CD4 (T4) antigen is an essential component of the receptor for the AIDS retrovirus," <i>Nature</i> 312:763-767, Macmillan Journals Ltd. (1984).
	AS	<u>2</u>	Demirov, D.G., <i>et al.</i> , "The Late Domain of Human Immunodeficiency Virus Type 1 p6 Promotes Virus Release in a Cell Type-Dependent Manner," <i>J. Virol.</i> 76:105-117, American Society for Microbiology (January 2002).
	AT	<u>2</u>	Devereux, J., <i>et al.</i> , "A comprehensive set of sequence analysis programs for the VAX," <i>Nucl. Acids Res.</i> 12:387-395, IRL Press Limited (1984).

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	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>3</u>	Erickson-Viitanen, S., <i>et al.</i> , "Cleavage of HIV-1 gag Polyprotein Synthesized In Vitro: Sequential Cleavage by the Viral Protease," <i>AIDS Res. Hum. Retroviruses</i> 5:577-591, Mary Ann Liebert, Inc. (1989).
	AS	<u>3</u>	Fujioka, T., and Kashiwada, Y., "Anti-AIDS Agents, 11. Betulinic Acid and Platanic Acid as Anti-HIV Principles from <i>Syzygium claviflorum</i> , and the Anti-HIV Activity of Structurally Related Triterpenoids," <i>J. Nat. Prod.</i> 57:243-247, American Society of Pharmacognosy and the Lloyd Library and Museum (1994).
	AT	<u>3</u>	Garrus, J.E., <i>et al.</i> , "Tsg101 and the Vacuolar Protein Sorting Pathway Are Essential for HIV-1 Budding," <i>Cell</i> 107:55-65, Cell Press (2001).

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	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>4</u>	Haan, K., "HIV gags on PA-457," <i>BioCentury, The Bernstein Report on BioBusiness</i> : Page A12 of 22, Biocentury Publications, Inc. (October 27, 2003 issue).
	AS	<u>4</u>	Hopp, T.P., <i>et al.</i> , "A Short Polypeptide Marker Sequence Useful for Recombinant Protein Identification and Purification," <i>Biotechnology</i> 6:1204-1210, Nature Publishing Co. (1988).
	AT	<u>4</u>	Kanamoto, T., <i>et al.</i> , "Anti-Human Immunodeficiency Virus Activity of YK-FH312 (a Betulinic Acid Derivative), a Novel Compound Blocking Viral Maturation," <i>Antimicrob. Agents Chemother.</i> 45:1225-1230, American Society for Microbiology (2001).

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	AP						Yes No

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	AR	<u>5</u>	Kashiwada, Y., <i>et al.</i> , "Betulinic Acid and Dihydrobetulinic Acid Derivatives as Potent Anti-HIV Agents," <i>J. Med. Chem.</i> 39:1016-1017, American Chemical Society (1996).
	AS	<u>5</u>	Kashiwada, Y., <i>et al.</i> , "Anti-AIDS Agents. 30. Anti-HIV Activity of Oleanolic Acid, Pomolic Acid, and Structurally Related Triterpenoids," <i>J. Nat. Prod.</i> 61:1090-1095, American Chemical Society and American Society of Pharmacognosy (1998).
	AT	<u>5</u>	Kashiwada, Y., <i>et al.</i> , "Anti-AIDS Agents 38. Anti-HIV Activity of 3-O-Acyl Ursolic Acid Derivatives," <i>J. Nat. Prod.</i> 63:1619-1622, American Chemical Society and American Society of Pharmacognosy (2000).

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>6</u>	Kashiwada, Y., <i>et al.</i> , "Synthesis and Anti-HIV Activity of 3-Alkylamido-3-deoxy-betulinic Acid Derivatives," <i>Chem. Pharm. Bull.</i> 48:1387-1390, Pharmaceutical Society of Japan (2000).
	AS	<u>6</u>	Kohl, N.E., <i>et al.</i> , "Active human immunodeficiency virus protease is required for viral infectivity," <i>Proc. Natl. Acad. Sci. USA</i> 85:4686-4690, National Academy of Sciences (1988).
	AT	<u>6</u>	Li, F., <i>et al.</i> , "PA-457: A potent HIV inhibitor that disrupts core condensation by targeting a late step in Gag processing," <i>Proc. Natl. Acad. Sci.</i> 100:13555-13560, National Academy of Sciences (November 2003).

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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>7</u>	Liang, C., <i>et al.</i> , "Deletion Mutagenesis within the Dimerization Initiation Site of Human Immunodeficiency Virus Type 1 Results in Delayed Processing of the p2 Peptide from Precursor Proteins," <i>J. Virol.</i> 73:6147-6151, American Society for Microbiology (1999).
	AS	<u>7</u>	Liang, C., <i>et al.</i> , "Characterization of a Putative $\alpha$ -Helix across the Capsid-SP1 Boundary That Is Critical for the Multimerization of Human Immunodeficiency Virus Type 1 Gag," <i>J. Virol.</i> 76:11729-11737, American Society for Microbiology (November 2002).
	AT	<u>7</u>	Pettit, S.C., <i>et al.</i> , "The p2 Domain of Human Immunodeficiency Virus Type 1 Gag Regulates Sequential Proteolytic Processing and Is Required To Produce Fully Infectious Virions," <i>J. Virol.</i> 68:8017-8027, American Society for Microbiology (1994).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Pettit, S.C., <i>et al.</i> , "Replacement of the P1 Amino Acid of Human Immunodeficiency Virus Type 1 Gag Processing Sites Can Inhibit or Enhance the Rate of Cleavage by the Viral Protease," <i>J. Virol.</i> 76:10226-10233, American Society for Microbiology (October 2002).
	AS	8	Pinckard, R.N., <i>et al.</i> , "Factors Influencing the Immune Response. I. Effects of the Physical State of the Antigen and of Lymphoreticular Cell Proliferation on the Response to Intravenous Injection of Bovine Serum Albumin in Rabbits," <i>Clin. Exp. Immunol.</i> 2:331-341, Blackwell Scientific Publications (1967).
	AT	8	Pokrovskii, A.G., <i>et al.</i> , "Synthesis of derivatives of plant triterpenes and study of their antiviral and immunostimulating activity," <i>Khimiya v Interesakh Ustoichivogo Razvitiya</i> 9:485-491, Siberian Branch of the Russian Academy of Sciences (2001).

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## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>9</u>	Robbins, D.C., <i>et al.</i> , "Antibodies to Covalent Aggregates of Insulin in Blood of Insulin-Using Diabetic Patients," <i>Diabetes</i> 36:838-841, American Diabetes Association (1987).
	AS	<u>9</u>	Sakalian, M., <i>et al.</i> , "The Mason-Pfizer Monkey Virus Internal Scaffold Domain Enables In Vitro Assembly of Human Immunodeficiency Virus Type 1 Gag," <i>J. Virol.</i> 76:10811-10820, American Society for Microbiology (November 2002).
	AT	<u>9</u>	Sandefur, S., <i>et al.</i> , "The I Domain Is Required for Efficient Plasma Membrane Binding of Human Immunodeficiency Virus Type 1 Pr55 <sup>Gag</sup> ," <i>J. Virol.</i> 72:2723-2732, American Society for Microbiology (1998).

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	AR	<u>10</u>	Sidhu, M.K., <i>et al.</i> , "Distinction Between HIV-1 and HIV-2 Nucleotide Sequences by PCR and Restriction Enzyme Analysis," <i>Biotechniques</i> 18:20-24, Eaton Publishing Co. (1995).
	AS	<u>10</u>	Smith, T.F., and Waterman, M.S., "Comparison of Biosequences," <i>Adv. Appl. Mathematics</i> 2:482-489, Academic Press, Inc. (1981).
	AT	<u>10</u>	Wiegers, K., <i>et al.</i> , "Sequential Steps in Human Immunodeficiency Virus Particle Maturation Revealed by Alterations of Individual Gag Polyprotein Cleavage Sites," <i>J. Virol.</i> 72:2846-2854, American Society for Microbiology (1998).

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	AP						Yes No

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	AR	<u>11</u>	Wild, C.T., <i>et al.</i> , "In vitro and <i>in vivo</i> pre-clinical analyses of PA-457, a novel betulinic acid derivative that potently inhibits HIV-1 replication," <i>AIDS 2002 Barcelona, XIV International AIDS Conference</i> , Abstract MoPeA3030, International AIDS Conference (July 2002).
	AS	<u>11</u>	Zhou, J., <i>et al.</i> , "Small-Molecule Inhibition of Human Immunodeficiency Virus Type 1 Replication by Specific Targeting of the Final Step of Virion Maturation," <i>J. Virol.</i> 78:922-929, American Society for Microbiology (January 2004).
	AT	<u>11</u>	Zhu, Y.-M., <i>et al.</i> , "Synthesis and Anti-HIV Activity of Oleanolic Acid Derivatives," <i>Bioorg. Med. Chem. Lett.</i> 11:3115-3118, Elsevier Science Ltd. (2001).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
	AB						
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	AD						
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	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

## FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	<u>12</u>	Database CAPLUS, Accession Number 2001:541179, English language abstract for Pokrovskii, A.G., <i>et al.</i> , (Document AT8), published by The American Chemical Society on STN.
	AS	<u>12</u>	Pending Non-Provisional United States Patent Application No. 10/670,797, Allaway <i>et al.</i> , filed September 26, 2003 (NOT PUBLISHED).
	AT	<u>12</u>	Pending Non-Provisional United States Patent Application No. 10/851,637, Salwedel <i>et al.</i> , filed May 24, 2004 (NOT PUBLISHED).

EXAMINER	DATE CONSIDERED
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FORM PTO-1449 <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 1900.0430002/LBB/SJE	APPLICATION NO. 10/766,528
	FIRST NAMED INVENTOR SALZWEDEL <i>et al.</i>	
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	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

	AR	<u>13</u>	NCBI Entrez, GenBank Report, Accession No. M17451, Starcich, B.R., <i>et al.</i> , National Center for Biotechnology Information (1993).
	AS	<u>13</u>	NCBI Entrez, GenBank Report, Accession No. M19921, Adachi, A., <i>et al.</i> , National Center for Biotechnology Information (1993).
	AT	<u>13</u>	Dialog File 351, Accession Number 7938971, Derwent WPI English language abstract for JP 1-143832 (Document AL1).

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